



AMERICA'S ESSENTIAL HOSPITALS

September 13, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: CMS-1772-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the above-captioned proposed rule. America's Essential Hospitals appreciates the Centers for Medicare & Medicaid Services' (CMS') work to improve the delivery of high-quality, integrated health care across the continuum and to close the existing health equity gap. As the agency finalizes Medicare outpatient payment policies, we ask that it consider the following comments on supporting the unique role essential hospitals play in promoting health equity and increasing access for marginalized communities by crafting policies that protect these hospitals from payment cuts and ensure their continued stability. In addition, now that the U.S. Supreme Court has unanimously spoken on the issue, we call on CMS to swiftly restore full Part B drug payment rates for hospitals in the 340B Drug Pricing Program and to institute a remedy making 340B hospitals whole for the five years of cuts. Further, given the continued impact of COVID-19 and its unknown effect on underlying measure data, it is important CMS be thoughtful in its future publishing of Overall Hospital Star Ratings.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.9 percent on average compared with 8.8 percent for all

hospitals nationwide.¹ These narrow operating margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19. Throughout the pandemic, essential hospitals have been on the front lines screening, vaccinating, testing, and treating COVID-19 patients in their communities. As essential hospitals attempt to rebound from the pandemic, they remain prepared for new surges while facing new challenges, such as rising workforce costs and shortages, rising supply costs, and supply shortages.

Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and more than 22 million live below the poverty line.² Essential hospitals are uniquely situated to target these social determinants of health (SDOH) and are committed to serving these marginalized patients. These circumstances, however, compound our members' challenges and strain their resources, requiring flexibility to ensure essential hospitals are not unfairly disadvantaged for serving marginalized populations and can continue to provide vital services in their communities.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. These ambulatory networks are a central part of essential hospitals' efforts to address the structural racism ingrained in the health care system at large by bringing culturally competent care to patients who otherwise lack access to care. These networks allow essential hospitals to bring care closer to where their underserved patients live, which is an important step in ensuring continuity of care for patients whose health is shaped by lack of transportation, unstable housing, and other social risk factors. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs. These ambulatory networks have been a critical asset in essential hospitals' response to COVID-19, as well.

We are deeply concerned about several provisions of the proposed rule that would have a disproportionately negative impact on essential hospitals, which are committed to combating inequities that lead to health disparities among underrepresented populations. The insufficient outpatient payment update, coupled with the cuts to off-campus provider-based departments (PBDs), will impede the ability of essential hospitals to remain financially solvent. This will undermine their ability to serve as primary points of care in underserved communities, including for people of color and others disproportionately affected by public health crises, such as COVID-19.

As the nation continues to respond to the pandemic and faces the emerging monkeypox public health emergency, we urge the agency to implement policies that will ensure stability for hospitals serving marginalized patients and promoting health equity. We are pleased by CMS' stated intention to revert to the full Part B drug payment rate for 340B hospitals. Returning to the full payment rate will be necessary to maintain parity in drug payment rates across all

¹ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2019 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2021. <https://essentialdata.info>. Accessed September 6, 2022.

² Ibid.

hospitals and ensure essential hospitals can continue to fulfill their mission with limited resources. But CMS must swiftly craft a remedy to make 340B hospitals whole for the five years and billions of dollars of cuts that already have caused substantial harm to these hospitals, which treat disproportionate numbers of low-income patients, and weakened their ability to offer heavily discounted drugs to patients to counter rapidly increasing drug prices. To ensure our members have sufficient resources to respond to future outbreaks of COVID-19 and meet new challenges and are not unfairly disadvantaged by their commitment to complex patients, CMS should consider the following recommendations when finalizing the above-mentioned proposed rule.

- 1. CMS should define the category of hospitals that promote equitable care and serve marginalized patients and implement policies that will protect and support these essential hospitals' critical work.**

CMS should adopt payment policies that recognize the unique role of essential hospitals in promoting health equity and should protect essential hospitals from the adverse effects of payment cuts and other policies that affect patient access.

The administration has prioritized the importance of tackling structural racism and promoting equity throughout the federal government.³ The administration expresses commitment to equity throughout the rule in its proposals and requests for information related to quality measures, rural hospital payment, and other issues. From low payment rates in Medicare and Medicaid—insurance on which low-income people rely—to worse health outcomes for people of color, the lingering effects of structural racism drive health disparities and represent a continued public health threat. Recent research underscores the magnitude of this chronic underfunding of hospitals that serve people of color, finding that hospitals serving the highest share of Black patients received starkly lower payments than other hospitals—on average \$26 million less per Black-serving hospital.⁴

Essential hospitals are at the center of the health care safety net—by virtue of their very mission and diverse communities, they are experts in addressing SDOH and advancing health equity. This expertise stems from their firsthand experience witnessing and tackling the effects of structural racism and how it routinely disadvantages and produces cumulative and chronic adverse outcomes for people of color, who made up half of member discharges in 2019. Patients of essential hospitals are negatively impacted by SDOH that affect their health, well-being, and quality of life.

As essential hospitals, our members are committed to ending health disparities and providing high-quality care to all, including underrepresented and marginalized populations. But the ability to sustain this critical work is hampered by challenges essential hospitals face, including financial instability driven by insufficient payments and skyrocketing costs. Essential hospitals are chronically underfunded, due to their lower share of commercially insured patients relative to other hospitals, their high level of uninsured patients and patients insured by public payers, the disproportionately high amount of uncompensated care they provide, and the volatility of the disparate payment sources on which they rely. Federal policy changes, such as Medicare

³ Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, E.O. 13985. January 20, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>. Accessed September 1, 2022.

⁴ Himmelsstein, G, Caesar JN, Himmelsstein, KEW. Hospitals That Serve Many Black Patients Have Lower Revenues and Profits: Structural Racism in Hospital Financing. *Journal of General Internal Medicine*. 2022. <https://doi.org/10.1007/s11606-022-07562-w>. Accessed August 14, 2022.

payment cuts, disproportionately impact these hospitals, which already operate on financial margins narrower than the average hospital. Such policy changes also undermine Medicare beneficiaries' access to the linguistically and culturally competent care essential hospitals provide. **To further the administration's and essential hospitals' shared goals of tackling health disparities and promoting health equity, it is imperative CMS recognize these hospitals when crafting Medicare payment and other policies.**

- a. CMS first should define the select group of hospitals with a safety net mission that provide a substantial share of uncompensated care and serve a high number of low-income patients.

CMS can begin this work by defining this select group of hospitals. Essential hospitals are distinguished by the diverse patients they treat, serving high proportions of Medicaid, Medicare, and uninsured patients, in addition to racial and ethnic minorities. Due to their payer mix, they also provide a much higher share of uncompensated care and have far fewer commercially insured patients than the average hospital. Although the more than 300 essential hospitals represent only 5 percent of all hospitals nationwide, they provide about 17 percent of all uncompensated care nationally. On a per-hospital basis, that translates to about seven times as much uncompensated care at the average essential hospital than at other hospitals -- about \$56 million versus about \$8 million annually.⁵ In addition to this vital safety net role, essential hospitals serve other key roles in their communities. They:

- provide specialized, lifesaving services, such as level I trauma and neonatal intensive care, emergency psychiatric services, and burn treatment;
- train the next generation of health care professionals to ensure the community's supply of doctors, nurses, and other caregivers meets demand;
- deliver comprehensive, coordinated care across large ambulatory networks to bring services to where patients live and work;
- meet public health needs by improving population health and preparing for and responding to natural disasters, public health emergencies, and other crises; and
- advance health equity to meet the needs and challenges of patient populations that face the greatest disparities and barriers to receiving quality care.

By providing this array of services, essential hospitals serve as anchor institutions and providers of choice for their communities. With a clear definition, CMS can identify providers that fill these specific roles in the health care system and assess how current and future Medicare policies impact them. This identification will ensure CMS can target support to this specific group of hospitals and protect them from harmful policies.

- a. Once CMS has defined this group of hospitals, the agency should implement policies throughout the Medicare program that can support these hospitals and change those policies that disproportionately harm them.

Once CMS defines this group of hospitals, we urge the agency to identify new policies that will ensure stable funding to these hospitals and evaluate current policies that might disproportionately harm them. For example, as we outline in more

⁵ Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2019 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2021. <https://essentialdata.info>. Accessed September 6, 2022.

detail in the sections below, there are certain areas in the proposed rule where CMS could develop policies targeted to essential hospitals:

- ensuring stable access for low-income patients to ambulatory networks by exempting essential hospitals from excepted off-campus PBD clinic visit cuts;
- ensuring access for low-income patients to ambulatory networks by ensuring an adequate payment rate for non-excepted, off-campus PBDs of essential hospitals; and
- adding hospital characteristics, including classification as an essential hospital, to the confidential reporting of disparity method results.

CMS can use its existing statutory authority to implement these changes. The Medicare statute gives CMS wide latitude to implement these changes. There is precedent both in this rule, as well as in previous rulemaking, for CMS to protect certain hospitals from financial losses or to increase payments to all hospitals or groups of hospitals.

In working to identify and support essential hospitals, CMS would advance its commitment to health equity, protect the interests of the Medicare program, and preserve access to care for the most disadvantaged Medicare beneficiaries. **In addition to implementing our specific recommendations throughout this letter, CMS should continue this work in future rulemaking to evaluate policies to support and protect these hospitals serving a safety net role. We urge CMS to follow these recommendations, and we look forward to working with the agency to advance our shared goals.**

2. CMS should increase its proposed annual hospital payment update to account for rapidly rising costs of hospital goods and services.

CMS proposes a net annual payment update of 2.7 percent, resulting from a 3.1 percent market basket update minus a 0.4 percentage point productivity adjustment. **We urge CMS to adjust its methodology for calculating the annual payment update for calendar year (CY) 2023 to ensure it provides a robust payment update that adequately incorporates the effects of inflation and rising workforce costs on hospitals.**

Hospitals continue to incur soaring costs as they recover from the COVID-19 pandemic, feel the effects of inflation, experience unprecedented increases in labor costs, and encounter supply chain issues and shortages. One recent report cited hospitals' per-patient labor costs increasing 37 percent from 2019 to 2022.⁶ Essential hospitals, in particular, have incurred considerable costs associated with hiring bonuses, retention bonuses, and increased salaries to recruit and retain nurses and other staff in short supply. These challenges have persisted even as COVID-19–related hospitalizations decrease and stabilize. Ongoing challenges from the protracted battle against COVID-19 and the consequential emotional toll on staff remain evident. The pandemic has led to burnout on an unprecedented scale, and essential hospitals have expended significant resources to recruit and retain clinical and non-clinical staff—a costly undertaking in the already competitive marketplace for health care workers. One essential hospital shared that its staffing costs have increased by 300 percent within six months. Other essential hospitals are experiencing significant budget shortfalls in 2022 resulting from these financial pressures. A recent article in *The New York Times* underscored that these challenges remain for essential

⁶ Muoio, Dave. Hospitals' per patient labor spend increased 37% from 2019 to Q1 2022. Fierce Healthcare. May 12, 2022. <https://www.fiercehealthcare.com/providers/hospitals-patient-labor-spend-increased-37-2019-q1-2022>. Accessed August 16, 2022.

hospitals, especially as many high-risk patients seek delayed care for conditions that worsened during the pandemic.⁷

In the context of historical inflation and workforce challenges, a net 2.7 percent payment update is insufficient to truly capture year-over-year changes in hospital costs. **To that end, we encourage CMS to implement a fee schedule increase factor of at least 5 percent and to use its statutory authority to waive the productivity adjustment in CY 2023.** In determining the annual fee schedule increase factor for hospitals, CMS typically uses the inpatient market basket update figure. The CMS Office of the Actuary (OACT) estimates the inpatient market basket percentage increase, which reflects the annual change in the mix of goods and services used for providing inpatient hospital services. OACT's use of the IHS Global Inc. forecast of the market basket rate of increase clearly does not account for the true cost increases hospitals face. CMS notes in the proposed rule that as it typically does, by the time of the final rule, it will use the updated inpatient market basket update from the FY 2023 Inpatient Prospective Payment System (IPPS) final rule, which is 4.1 percent instead of the proposed 3.1 percent. While this would be a shift in the right direction, it is still wholly insufficient to keep pace with hospitals' rising input costs. CMS is not bound to use the IPPS market basket update. The Outpatient Prospective Payment System (OPPS) statutory provision at 1833(t)(3)(C)(iv) provides authority for CMS to deviate from the IPPS update by "substituting for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year." **Therefore, CMS could look to alternative sources of cost data, such as data from Medicare cost reports, as a truer representation of hospital-reported cost increases to support providing an outpatient fee schedule increase factor of at least 5 percent.**

CMS also should waive the negative 0.4 percent productivity adjustment. While statute requires this adjustment, given the ongoing COVID-19 public health declaration and the fact that many of essential hospitals' current financial challenges stem from the pandemic, CMS can invoke its Section 1135 waiver authority to waive the adjustment. By adjusting the annual fee schedule increase factor to account for increasing hospital input costs, CMS can ensure hospitals can continue to provide high-quality care and meet their patients' needs.

3. CMS should revert to paying 340B hospitals the statutory default payment of average sales price (ASP) plus 6 percent and promptly repay 340B hospitals for the five years of unlawful cuts. As held by the U.S. Supreme Court, CMS' payment methodology exceeds the agency's statutory authority, and the cuts to 340B hospitals have harmed low-income patients and the hospitals committed to treating them.

America's Essential Hospitals urges CMS to revert to its longstanding, pre-2018 methodology of paying all OPPS hospitals at ASP plus 6 percent and to expeditiously craft a remedy to make 340B hospitals whole for the past five years of payment cuts. The current policy is based on an unlawful application of CMS' authority to set payment rates for specified covered outpatient drugs (SCODs) under the Social Security Act (SSA) and has had devastating consequences for underserved communities.

⁷ Weiland N. Loss of Pandemic Aid Stresses Hospitals That Treat the Uninsured. *The New York Times*. May 2022. <https://www.nytimes.com/2022/05/01/us/politics/covid-aid-hospitals-uninsured.html>. Accessed August 16, 2022.

For five straight years, CMS has reimbursed certain separately payable drugs purchased through the 340B program at 77.5 percent of ASP, amounting to more than \$8 billion in reduced drug reimbursement. This policy represents a nearly 30 percent reduction in Part B payments from the statutory default methodology for hospitals in the 340B program, while hospitals not in the program continue to receive payment at 106 percent of ASP. In June, the Supreme Court unanimously struck down CMS' unlawful 2018 and 2019 policy, unequivocally holding that "under the text and structure of the statute, this case is therefore straightforward," and that "HHS acted unlawfully by reducing reimbursement rates for 340B hospitals."⁸ Since the Supreme Court remanded the case to the lower courts to determine the remedy, the parties to this case now are submitting briefing to the U.S. District Court for the District of Columbia on this issue.

CMS correctly recognizes the significance of the Supreme Court's decision. In that case, the Court held that "absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals" relative to other hospitals, and "HHS's 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful."⁹ This decisive ruling marks the culmination of yearslong litigation challenging CMS' authority to institute these cuts and resolves any doubt about whether these cuts can continue. As CMS acknowledges in its proposed rule, the Supreme Court's decision "obviously has implications for CY 2023 payment rates."¹⁰ **To that end, we support the agency's position that it "fully anticipates" reverting to its prior policy of paying ASP plus 6 percent for 340B-acquired drugs in CY 2023 and urge it to finalize this policy in the OPPS final rule.**

CMS also has requested comments on a remedy in the ongoing litigation. As we explain below, the Supreme Court's decision dictates that the only possible remedy is to:

- revert to the prior lawful policy of paying ASP plus 6 percent for CY 2023, regardless of whether a drug was acquired through the 340B program;
- promptly repay any hospital the difference between ASP plus 6 percent and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022, plus applicable interest; and
- hold the entire hospital field harmless for this illegal policy for CYs 2018-2022, which means no recoupment of funds received during this period.

We strongly encourage CMS to agree to this remedy in the ongoing litigation and to ensure that payments to hospitals are appropriately restored in the agency's CY 2023 OPPS final rule. Below we provide additional recommendations on a remedy, as well as future payment levels that will adequately compensate 340B hospitals and support, rather than undermine, our shared priorities of addressing health inequities and promoting the health of the nation's marginalized communities.

Further, we strongly urge CMS to stop its unlawful underpayments for the remainder of CY 2022 and apply the same payment rate to 340B hospitals that currently apply to all other hospitals. There is no defensible reason to continue harming 340B hospitals with a clearly unlawful policy. CMS has administrative procedures available to it to enable a swift correction of the payment rates, including the ability to issue an interim final

⁸ American Hospital Association et al. v. Becerra 596 U.S. ___, slip op. at 10 (2022).

⁹ Id. at 14.

¹⁰ CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44647 (July 26, 2022).

rule. If CMS determines—despite arguments reiterated in the plaintiffs’ recent brief to the District Court¹¹ and below—that it must make budget neutrality adjustments for this return to lawful payment rates, those issues can be resolved separately, including as part of its work on remedy.

- a. As it anticipates, CMS should pay ASP plus 6 percent for 340B-acquired drugs for CY 2023.

The proposed rule explains that “in light of the Supreme Court’s recent decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program for CY 2023.”¹² **America’s Essential Hospitals supports this policy.** Having failed to conduct the required cost acquisition survey, CMS is correct that, under the Supreme Court’s decision, it may not vary reimbursement rates for 340B hospitals for CY 2023 and therefore must pay 340B hospitals at the ASP plus 6 percent rate. **We urge CMS to follow through with this anticipated policy in its final rule.**

By ending these cuts to safety net providers once and for all, the agency will align with the Biden administration’s priorities of addressing health inequities and promoting the health of the nation’s marginalized communities. We urge CMS to ensure continuity in the ASP plus 6 percent payment rate going forward to maintain adequate funding and parity for 340B hospitals. That is, CMS should ensure they are paid at 106 percent of ASP, as had been the case before 2018, and should not vary payment rates using its faulty 2020 acquisition cost survey or any future acquisition cost survey. Adequate and equitable reimbursement will be consistent with the intent of the 340B program and vital for these hospitals serving a safety net role to continue to serve the marginalized communities that turn to them for care.

Congress created the 340B program, codified in the Public Health Service Act, to allow covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹³ Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings critical to the operations of hospitals that fill a safety net role. These savings also enable essential hospitals to address the social determinants shaping their patients’ health, such as food insecurity, homelessness, and lack of transportation. Essential hospitals reinvest 340B savings into programs to coordinate care and improve outcomes for disadvantaged populations, including initiatives to reduce readmissions, ensure medication compliance, and identify high-risk patients in need of ancillary services.

Statute structures the 340B program to offer hospitals discounts for covered outpatient drugs provided to patients of a covered entity, regardless of a patient’s insurance status. Congress plainly expected that various public and private payers would reimburse hospitals at rates higher than the cost of the discounted drugs they receive from manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services, as explained in our comments below. The Supreme Court acknowledged this very point in its opinion, stating that in setting Part B drug reimbursement rates in 2003, “Congress was well aware that 340B hospitals paid less for covered prescription drugs” but “did not see fit

¹¹ Reply in Support of Plaintiffs’ Motion to Vacate the Unlawful Portion of the 2022 OPPTS Rule, *American Hospital Association et al. v. Becerra*, Case 1:18-cv-02084-RC, Document 75, filed Aug. 17, 2022.

¹² CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44648 (July 26, 2022).

¹³ H.R. Rep. No. 102–384, pt. 2 (1992).

to differentiate 340B hospitals from other hospitals when requiring that the reimbursement rates be uniform under option 2.”¹⁴

As America’s Essential Hospitals has expressed in its comments in previous years, in addition to being unlawful and undercutting health equity initiatives, paying 340B hospitals at a lower rate than non-340B hospitals is a counterproductive policy for several reasons:

- Reduced payments jeopardize the patchwork support on which essential hospitals rely, threatening their ability to maintain critical services. 340B hospitals’ Medicare outpatient margins are substantially lower than non-340B hospitals. Reducing OPPS reimbursement through Part B payment reductions widens this spread in margins between 340B and non-340B hospitals;
- Patients do not benefit from CMS’ payment cuts. Because CMS implements this policy in a budget-neutral manner that raises OPSS rates for other ambulatory payment classifications, all beneficiaries pay higher copays for other services. Additionally, most beneficiaries have some form of third-party coverage that covers unpaid Medicare copays; and
- The payment cuts undermine the administration’s efforts to counter astronomically rising drug prices. While the evidence is clear that drug list prices have risen from year to year, CMS provides no evidence of how lowering reimbursement to 340B hospitals for separately payable drugs under the OPSS would counter this trend. The 340B program actually saves money for providers, patients, and the federal government. It is a critical tool that insulates patients from rising drug prices and ensures their continued access to needed therapeutics.

It is difficult to justify this policy, which reduces the benefit of the 340B program, while threatening the ability of participating hospitals to provide care to marginalized Medicare beneficiaries and other patients. The reduction in payments to 340B hospitals has had negative consequences for essential hospitals and their patients; therefore, **we strongly urge the agency to withdraw this policy once and for all and revert to paying 340B hospitals at 106 percent of ASP.** We believe preserving the intent of the 340B program would better serve low-income Medicare beneficiaries and the Medicare program at large and align with the administration’s policy goals.

- b. CMS should discontinue use of the JG and TB claims modifiers to identify drugs acquired with a 340B discount.

To identify which Part B drugs are subject to the reimbursement cuts, CMS has required since January 1, 2018, the use of claims modifiers JG and TB on OPSS claims with 340B-acquired drugs. CMS uses the JG modifier to reduce reimbursement for 340B drugs and the TB modifier as an informational modifier on claims for 340B drugs not subject to the payment reduction (e.g., pass-through drugs and drugs administered at exempt hospitals, such as rural sole community hospitals). Because CMS plans to revert to its pre-2018 policy, it no longer needs to distinguish between 340B and non-340B drugs. The use of these modifiers has been burdensome for hospitals, as they require hospitals to distinguish their 340B discounted drugs and non-340B drugs, as well as between 340B drugs subject to the payment reduction and those 340B drugs not subject to the payment reduction. The difficulty is further compounded in cases when 340B hospitals purchase drugs at list price, or wholesale acquisition cost, due to being unable to purchase drugs through a group purchasing organization. **Because the use of**

¹⁴ *American Hospital Association et al. v. Becerra* 596 U.S. ___, slip op. at 12 (2022).

these modifiers will no longer be relevant when CMS reverts to paying at ASP plus 6 percent, we urge CMS to discontinue their burdensome use.

- c. CMS should revise its negative budget neutrality adjustment associated with reverting to 106 percent of ASP to be equal to the budget neutrality adjustment that CMS has applied for the past five years the policy has been in place.

CMS should maintain budget neutrality in OPSS payments in 2023 onward by decreasing the conversion factor by 3.2 percent, which would be a straightforward reversal of its 2018 conversion factor increase of the same amount. To keep its Part B drug reimbursement reduction budget-neutral, CMS in CY 2018 implemented a conversion factor update of 3.2 percent. That is, to keep overall OPSS payments budget-neutral, it increased OPSS payment rates for non-drug ambulatory payment classifications (APCs) to offset the decrease in drug payments. In the CY 2018 OPSS final rule, CMS estimated that the reduction in drug payments would be \$1.6 billion, requiring a 3.2 percent conversion factor increase to offset this payment reduction. This resulted in increased payment for hospitals for other OPSS items and services and maintained budget neutrality within the OPSS. Now, because CMS says it will unwind the Part B cuts to 340B hospitals in 2023, it will reverse the conversion factor increase by applying a negative budget neutrality adjustment to offset the anticipated increase in Part B drug payments. However, instead of merely reversing the 3.2 percent conversion factor update that has been in place in 2018, CMS recalculates the expected Part B drug payment increase in 2023, which it estimates would be \$1.96 billion. The agency says to offset this expected increase, it will require a conversion factor decrease of 4.04 percent. **We urge CMS to revisit this policy in the final rule and to maintain budget neutrality in 2023 onward by reducing the conversion factor by the same amount it has been increased by for the past five years—3.2 percent.**

Since CMS implemented the 3.2 percent conversion factor update in 2018, it has kept it in place without modification, notwithstanding the fact that the aggregate dollar amount of the Part B drug payment reduction has increased over the years, which would have necessitated a larger conversion factor increase. During those five years, being fully aware of the increase in the magnitude of the payment cut, CMS did not choose to update its conversion factor to ensure it was adequately offsetting the decrease in drug payments with higher payments for non-drug items and services. Recalculating and then increasing the magnitude of the negative adjustment will harm all hospitals paid under the OPSS by decreasing their non-drug payments more than is warranted to reverse the 2018 policy. For CMS to increase the payment offset, when it failed to increase the offset in previous years while it continued to cut payments to 340B hospitals, would be a mid-course policy shift detrimental to hospitals. To undo the policy that it has had in place since 2018, CMS simply should roll back the 3.2 percent conversion factor increase from 2018, which will reinstitute the pre-2018 OPSS payment rates.

Putting aside the patent unfairness of recalculating the conversion factor update amount without having given hospitals the benefit of a higher conversion factor update in previous years, this policy would devastate hospitals amid increasing labor costs, supply shortages, and skyrocketing costs for other goods and services. Implementing a 4.04 percent decrease, instead of the 3.2 percent decrease CMS should implement, would result in \$410 million less in OPSS payments in 2023. Moreover, the conversion factor update remains in place in perpetuity, so the repercussions of this inequitable adjustment would resonate with hospitals permanently. **Therefore, we call on CMS to simply reverse the conversion factor increase that has been in effect for the past five years instead of increasing the size of its budget neutrality adjustment.**

d. CMS must promptly repay 340B hospitals for unlawful underpayments from 2018 to 2022, plus applicable interest.

CMS has sought public comment on “the best way to craft any potential remedies” for its unlawful reimbursement cuts from 2018 to 2022.¹⁵ But, there is only one way for CMS to fix the statutory violation the Supreme Court identified: eliminate its unlawful exception cutting rates for 340B hospitals and promptly pay 340B hospitals the difference between the amounts previously paid for 340B drugs and the default rate of ASP plus 6 percent (plus applicable interest) for all years in which CMS acted unlawfully. The Supreme Court recognized that “340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support.”¹⁶ Yet, for five years, CMS deprived 340B hospitals of this limited funding. During that period, 340B hospitals struggled to care for patients amid a once-in-a-century pandemic. Speedy repayment to 340B hospitals is crucial. To be clear, under no circumstances should a remedy involve a new survey of acquisition costs, which not only would cause significant delay and further hardship to 340B hospitals, but worse, would ignore the Supreme Court’s unanimous conclusion that a survey is a “prerequisite for varying reimbursement rates by hospital group” and its unanimous order to adopt a remedy “consistent with this opinion.”¹⁷ CMS cannot retroactively cure its past unlawful conduct with a new survey.

It is not entirely clear why the agency needs public comment to determine the remedy in *American Hospital Association et al. v. Becerra*. That remedy, which will be decided in the context of the ongoing litigation and not in any separate rulemaking proceeding for cost year 2023, is straightforwardly dictated by the reasoning of the Supreme Court’s decision. As noted, the Court invalidated the rate reductions for 2018 and 2019 because “the statute does not grant HHS authority to vary the reimbursement rates by hospital group.”¹⁸ The 2018 and 2019 OPPS rules that were formally before the Supreme Court did just that: both varied the payment rates for the same drugs depending on whether they were acquired by 340B hospitals without relying on a statutorily required cost acquisition survey. The 2020, 2021, and 2022 OPPS rules did the same thing.

The Supreme Court’s decision, therefore, dictates what CMS must do to fix its violations. **CMS must now reimburse 340B drugs each year at the same rate used for non-340B drugs that year. For every year from 2018 through 2022, CMS has already decided the payment rate for non-340B drugs: ASP plus 6 percent. CMS needs now to match that rate for 340B drugs, a proposition with which CMS appears to agree.**¹⁹ It therefore must now craft a remedy that promptly repays 340B hospitals the difference between what they were previously paid and ASP plus 6 percent for CYs 2018 to 2022.

Because CMS “fully anticipates” reverting to its prior policy of ASP plus 6 percent for 340B-acquired drugs in cost year 2023, and because the proposed rule nowhere mentions its 2020

¹⁵ CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44649 (July 26, 2022).

¹⁶ *American Hospital Association et al. v. Becerra* 596 U.S. ___, slip op. at 13 (2022).

¹⁷ *American Hospital Association et al. v. Becerra* 596 U.S. ___, slip op. at 13 (2022).

¹⁸ *American Hospital Association et al. v. Becerra* 596 U.S. ___, slip op. at 12 (2022).

¹⁹ See CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44647 (“We fully anticipate applying a rate of ASP+6 percent to [340B drugs] in the final rule for CY 2023, in light of the Supreme Court’s recent decision.”); *Am. Hosp. Ass’n v. Hargan*, No. 17-2447, ECF No. 18 at 49 (D.D.C., filed Dec. 1, 2017) (if plaintiffs were to ultimately prevail, they could obtain “an order directing [CMS] to reinstate the ASP+6% OPPS payment rate for 340B drugs”).

survey in connection with cost year 2023, we assume CMS has come to recognize the fatal flaws in that survey. However, the proposed rule does briefly note CMS once stated that “a remedy that relies on such survey data could avoid the complexities referenced in the district court’s opinion.”²⁰ We assume CMS is merely recounting the history of this issue because the law is clear: **CMS may not rely on its defective 2020 survey in connection with the remedy for underpaying 340B hospitals.**

Reliance on CMS’s 2020 survey in connection with any remedy would be unlawful. As America’s Essential Hospitals and others have previously explained, CMS’s survey did not comply with 42 U.S.C. 1395l(t)(14)(D)(iii).²¹ We need not catalogue all the survey’s flaws again, but it is important to restate that the survey was issued during the height of the COVID-19 pandemic, while 340B hospitals were struggling to marshal critical resources to respond to the pandemic. Given that timing, CMS unsurprisingly received actual acquisition-cost data “for each individual” drug from only 7 percent of those surveyed.²² Of the remaining hospitals surveyed, 38 percent did not respond and an additional 55 percent opted for a so-called “quick survey,” whereby CMS used 340B ceiling prices maintained by the Health Resources and Service Administration (HRSA) as a proxy for actual drug acquisition costs. With such a low response rate, it is apparent HHS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug. In addition, the agency surveyed only 340B hospitals, but nowhere in the statute does Congress give HHS the authority to collect acquisition cost data from only a specific subset of all hospitals. Taken together, these design and execution flaws make clear CMS did not, as the law requires, survey “a large sample of hospitals that is sufficient to generate a statistically significant estimate.”²³

Perhaps for this reason, CMS never has relied on this survey—including in the current CY 2023 proposed rule. It would be both unfair and unlawful for the agency to rely on it now as part of a retrospective remedy. As an initial matter, the agency should not use a survey it explicitly chose not to rely on in CY 2021 and CY 2022. More fundamentally, any attempt to rely on the 2020 survey to set reimbursement rates for prior OPPS years would violate the Administrative Procedure Act (APA), which limits “rules” to agency prescriptions of “future effect.”²⁴ Having lost in the Supreme Court without ever relying on the defective survey, any attempt to rely on it as part of a backward-looking remedy would, as relevant case law makes clear, “make a mockery ... of the APA,” since “agencies would be free to violate the rulemaking requirements of the APA with impunity if, upon invalidation of a rule, they were free to ‘reissue’ that rule on a retroactive basis.”²⁵

²⁰ CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44649 (July 26, 2022).

²¹ See America’s Essential Hospitals Comment Letter on CY 2021 OPSS Proposed Rule. October 5, 2020. <https://essentialhospitals.org/wp-content/uploads/2020/10/AEH-CY2021-OPSS-Comment-Letter-10-5-20-unsigned.pdf>; American Hospital Association, Comment Letter on CMS–1736–P, Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs. October 5, 2020. <https://www.aha.org/system/files/media/file/2020/10/aha-comments-outpatient-pps-proposed-rule-for-cy-2021-letter-10-20.pdf>.

²² CY 2021 Outpatient Prospective Payment System final rule with comment period and interim final rule with comment period. 85 Fed. Reg. 85866 at 86044–86,045 (December 29, 2020).

²³ 42 U.S.C. 1395l(t)(14)(D)(iii).

²⁴ 5 U.S.C. § 551(4); see *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216–25, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988) (Scalia, J., concurring); *Bergerco Canada v. U.S. Treasury Department*, 129 F.3d 189, 192–93 (D.C. Cir. 1997) (treating Justice Scalia’s concurring opinion as substantially authoritative).

²⁵ *Georgetown Univ. Hosp. v. Bowen*. 821 F.2d 750, 758 (D.C. Cir. 1987) quoted in *Bowen*, 488 U.S. at 225 (Scalia, J., concurring).

Accordingly, CMS must craft a remedy that fully and promptly repays 340B hospitals for all the unlawful reimbursement cuts plus interest from 2018 through 2022.

- e. CMS should not seek to recoup funds from the rest of the hospital field as part of any remedy for its statutory violations.

CMS has previously invoked “budget neutrality” to argue that it may retrospectively recoup funds from hospitals as part of a remedy for its statutory violations. However, recoupment in the name of budget neutrality would be unlawful. **Nothing in federal law requires—or even authorizes—CMS to claw back funds to achieve budget neutrality. CMS’ prior legal arguments regarding budget neutrality are contrary to the text of the OPPS statute and contravene its own past practices.**

First, the text of the OPPS statute makes clear that budget neutrality applies prospectively—not retrospectively. Budget neutrality under the OPPS is an inherently prospective exercise; it avoids increases or decreases in “overall *projected* expenditures for *the next year*.”²⁶ Each year, the statute directs CMS to adjust the groups, relative payment weights, and wage indices in the OPPS for the upcoming year, accounting for changes in services, changes in technology, new cost data, and the like.²⁷ Any such changes must be budget-neutral, which means they cannot cause any change in “the *estimated amount* of expenditures . . . for the year.”²⁸ Thus, the plain text of the statute says nothing about past years or retrospective claw backs; instead, it only addresses future estimates and forward-looking periodic reviews.

The only provision of the OPPS statute that CMS previously cited in support of its budget-neutrality arguments is section 1395l(t)(14)(H).²⁹ But that provision relates to prospective budget neutrality and does not authorize the agency to retroactively recoup past payments as part of a remedy. Specifically, sub-paragraph (14)(H) simply requires that when CMS makes its usual prospective annual adjustments to the OPPS payment components under paragraph (t)(9) (payment groups, relative payment weights, wage adjustments, etc.), in the required budget neutral manner, CMS accounts for additional expenditures associated with implementation of the paragraph (14) drug APC payment methodology. To be clear, adjustments made under paragraph (9) whether related to paragraph (14) or otherwise, apply only to the upcoming year. Sub-paragraph (14)(H) in no way authorizes CMS to retroactively recoup payments already made in the name of budget neutrality.

Nowhere does the OPPS statute speak of budget neutrality in connection with retrospective changes. During the many years it has litigated *American Hospital Association et al. v. Becerra*, CMS has never identified a clear, express reference to retrospective recoupment in the statute’s budget neutrality provisions because CMS has no authority to recoup past payments to achieve budget neutrality. For example, the Supreme Court has previously stated, in the context of Medicare reimbursement, that “retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their

²⁶ *Am. Hosp. Ass’n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (emphasis added).

²⁷ 42 U.S.C. § 1395l(t)(9)(A).

²⁸ *Id.* § 1395l(t)(9)(B) (emphasis added); see also 2021 OPPS Rule, 85 Fed. Reg. at 86,054 (“OPPS budget neutrality is generally developed on a *prospective* basis by isolating the effect of any changes in payment policy or data under the OPPS with all other factors held constant.” (emphasis added))

²⁹ Defs’ Opp. Brief on Remedy, *Am. Hosp. Ass’n v. Azar*, No. 18-2084, ECF No. 36 at 10 (D.D.C., filed Feb. 14, 2019).

language requires this result.”³⁰ Elsewhere, HHS has recognized that any agency authority on retroactivity must be set forth in the kind of exceedingly clear statutory language that does not exist here.³¹

Second, although CMS frequently fixes prior errors in the OPSS, America’s Essential Hospitals cannot identify a single relevant instance in which CMS offset the cost of doing so by retroactively recouping prior payments to providers. Here are a few examples of CMS across prospective payment systems fixing prior errors without recouping prior payments to achieve budget neutrality:

- In 2007, HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality, an approach which the Court noted in *H. Lee Moffitt*;³²
- In 2015, CMS realized its OPSS payments in 2014 and 2015 had been too high because it had inaccurately increased the conversion factor when it began packaging clinical diagnostic laboratory tests into its OPSS payments rather than paying for them separately using the Clinical Laboratory Fee Schedule. Upon recognizing its error, CMS reduced the conversion factor beginning in 2016 to prevent further overpayments going forward, but it did “not recoup ‘overpayments’ made for CYs 2014 and 2015.”³³
- Within the context of IPPS, although annual area wage index adjustments must be budget-neutral,³⁴ CMS can revise a wage index in response to an adverse judicial decision without a need for corresponding changes to achieve budget neutrality.³⁵

We are aware of only a single instance when CMS, through a prospective adjustment, offset past overpayments caused by a policy change under a prospective payment system, but it did so only pursuant to express authorization from Congress. In that lone example, CMS changed certain documentation and coding policies under the IPPS for 2008 and recognized that those changes might lead to higher aggregate expenditures that did not reflect actual changes in services.³⁶ After CMS announced the changes, Congress acted twice to give CMS narrow, specific authority to reduce payment rates in future years to offset past overpayments caused by the policy changes.³⁷ Notably, Congress gave CMS express authority to apply budget neutrality, but even then, only through a prospective adjustment. Congress “knows exactly how” to give CMS express authority to offset past Medicare overpayments “when it wishes,” but did not do so here. ³⁸

³⁰ See *Bowen*, 488 U.S. at 208; see also *Claridge Apartments Co. v. Comm’r of Internal Revenue*, 323 U.S. 141, 164 (1944) (“Retroactivity, even where permissible, is not favored, *except upon the clearest mandate.*” (emphasis added)).

³¹ See Gov’t Memo., *H Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Price*, No. 1:16-cv-2337-TJK, ECF No. 16-1, at 25 (D.D.C., filed July 17, 2017) (“Generally, retroactive applications of a law are strongly disfavored, as they disrupt legitimate expectations and disturb settled transactions. Indeed, cases where the Supreme Court has truly found retroactive effect adequately authorized by a statute have involved statutory language that was so clear that it could sustain only one interpretation.” (cleaned up and citations omitted)).

³² 324 F. Supp. 3d at 15; See also 2007 OPSS Rule, 71 Fed. Reg. 67960, 68010 (Nov. 24, 2006).

³³ 2016 OPSS Rule, 80 Fed. Reg. 70,298, 70,354 (Nov. 13, 2015).

³⁴ 42 C.F.R. § 412.64(e)(1)(ii).

³⁵ See *id.* § 412.64(l).

³⁶ 2008 IPPS Rule, 72 Fed. Reg. 47,130, 47186 (Aug. 22, 2007).

³⁷ See TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–97 (2007); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013).

³⁸ *Ysleta Del Sur Pueblo v. Texas*, 142 S.Ct. 1929, 1942 (June 15, 2022); see generally *Brimstone R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928) (“The power to require readjustments for the past is

Given this statutory text and regulatory history, CMS has no authority to retrospectively recoup funds from the hospital field as part of any remedy in *American Hospital Association et al. v. Becerra*. Thus, not only would it be unfair and unwise to penalize hospitals for the agency’s mistakes in this way, it would be unlawful, as well. We urge CMS to implement a fair, effective, and lawful remedy promptly—without the cost, disruption, and distraction of many more years of litigation to finally put the prior unlawful policy behind it.

4. Communities served by essential hospitals face unique health and social challenges; CMS should account for these challenges and preserve adequate reimbursement rates for essential hospitals’ excepted and non-excepted PBDs.

We urge the agency to reverse course on certain site-neutral payment policies to PBDs, which disproportionately affect essential hospitals and the patients they serve. **CMS should use its authority to protect essential hospitals, as defined in section 1, from payment cuts to their PBDs. Specifically, CMS can exempt essential hospitals’ excepted, off-campus PBDs from the clinic visit policy and pay non-excepted, off-campus PBDs of essential hospitals subject to Section 603 of the Bipartisan Budget Act of 2015 (BBA) at a rate no lower than 75 percent of the OPSS rate.**

To align with the administration’s policy goals, the agency must revise its site-neutral policies to the fullest extent permitted by statute to protect essential hospitals and their patients, rather than causing further harm. Essential hospital PBDs are disproportionately impacted by site-neutral payment policies. For hospitals operating on narrow (often negative) margins, these substantially lower payments are unsustainable and will affect patient access in areas with the greatest need for these services. Essential hospitals operate on a negative 16 percent Medicare outpatient margin—9 percentage points lower than OPSS hospitals nationally. Continuing these cuts without revision would reduce essential hospitals’ outpatient margins even further.

Shielding essential hospital PBDs from the detrimental impact of these cuts would ensure essential hospital PBDs can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas and advance the administration’s health equity goals.

Given essential hospitals’ expansive networks of ambulatory care in otherwise underserved communities, site-neutral payments will continue to have a profound negative effect on their patients. In most communities, essential hospitals are the only providers willing to take on the financial risk of providing comprehensive care to low-income patients, including the uninsured and beneficiaries dually eligible for Medicare and Medicaid. PBDs enable hospitals to expand access for disadvantaged patients in communities with no other options for both basic and complex health care needs. Essential hospital PBDs often are the only clinics in low-income communities that provide full primary and specialty services. Inadequate payment rates affect patient access by limiting the ability of essential hospitals to bring health care into these communities of need. CMS’ implementation of Section 603—especially the inadequate payment rate—already has caused essential hospitals to re-evaluate plans to expand their provider networks into underserved areas.

drastic. It . . . ought not to be extended so as to permit unreasonably harsh action *without very plain words.*” (emphasis added)).

CMS' site-neutral payment policies have played an undeniable role in limiting health care access for the country's most disadvantaged patients and will only further exacerbate health disparities. Essential hospitals are committed to advancing the Biden administration's goal of advancing racial equity throughout the federal government, including by addressing health disparities.³⁹ The patients treated at essential hospitals' off-campus PBDs typically are low-income people and people of color. Compared with patients at other hospitals, a significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. Dual-eligible beneficiaries tend to be in poorer health status, more likely to be disabled, and costlier to treat compared with other Medicare beneficiaries.⁴⁰ In fact, CMS uses a hospital's proportion of dual-eligible beneficiaries as a proxy for adjusting the hospital readmission measures to recognize differences in sociodemographic factors. Excessively restrictive policies on essential hospitals' PBDs undoubtedly have downstream effects, including limiting patient access.

Essential hospital clinics often fill a void by providing the only source of primary and specialty care in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health care costs, including for the Medicare program, by efficiently providing coordinated care through ambulatory networks. Providing care in the outpatient setting allows hospitals to avoid unnecessary emergency department (ED) visits, manage patients with chronic conditions, provide follow-up care to patients to avoid readmissions, and, in the process, reduce costs for the health care system at large. These are goals CMS should promote, not stifle, through policies that protect patient access to vital clinic visits in essential hospital PBDs.

It also is worth noting there are key differences between PBDs and freestanding physician offices that warrant a higher payment rate for PBDs, generally. PBDs incur additional compliance costs freestanding physician offices do not bear. As integral parts of hospitals, PBDs must comply with provider-based regulations, which include requirements pertaining to billing, medical records, and staffing. For example, an outpatient department must be clinically and financially integrated with the main provider and offer full access to services at the main hospital to qualify as a provider-based facility and receive Medicare reimbursement. The department also must integrate its medical records into the main provider's system. Further, PBDs must maintain standby capacity to provide emergency services stemming from their obligations under the Emergency Medical Treatment and Active Labor Act of 1986 (EMTALA). They also undergo rigorous licensing and accreditation requirements, in addition to compliance with the Medicare conditions of participations, which freestanding physician offices are not bound by.

CMS has acknowledged it cannot directly compare payment to hospital PBDs and freestanding clinics because payment under the OPSS accounts for the cost of packaging ancillary services to a greater extent than payment under the Physician Fee Schedule (PFS). For many services paid under the OPSS, including comprehensive ambulatory payment classifications, CMS makes a single payment for the main service and related packaged services. Comparing payment under

³⁹ Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, E.O. 13985. January 20, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>. Accessed August 17, 2022.

⁴⁰ Medicare Payment Advisory Commission. *Data Book: Health Care Spending and The Medicare Program*. July 2022. https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_SEC_v2.pdf. Accessed August 14, 2022.

the OPSS and PFS without accounting for the higher level of packaging that occurs under the OPSS understates the costs of services in hospital PBDs.

The Medicare Payment Advisory Commission (MedPAC) in a June 2022 report discussed equalizing payment across ambulatory settings. MedPAC noted that adjustment in payment rates to hospital PBDs should account for the higher level of packaging in the hospital setting by paying the hospital department at a higher rate than the physician freestanding office. The report also acknowledged that low-income beneficiaries rely on PBDs as their primary source of care, and that site neutral payment policies targeting these PBDs could adversely affect access for low-income beneficiaries, necessitating policy adjustments to protect such PBDs.

- a. CMS can use its authority under Section 603 of the BBA to set an appropriate payment rate for non-excepted PBDs of essential hospitals.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying certain off-campus PBDs under the OPSS. The BBA instructed CMS to pay these non-excepted PBDs under a Part B “applicable payment system” other than the OPSS but not did prescribe a specific payment system or amount; CMS determined the PFS to be such a system and has the authority to determine the payment rates within that payment system. **America’s Essential Hospitals urges CMS to reimburse non-excepted PBDs of essential hospitals at no lower than 75 percent of the equivalent OPSS payment rate.** Doing so would ensure essential hospital PBDs can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas and advance the administration’s health equity goals.

Since 2018, CMS has established an interim payment rate under the PFS for non-excepted items and services provided at non-excepted off-campus PBDs that is equivalent to 40 percent of the OPSS payment rate. To public knowledge, CMS has not analyzed how reduced reimbursement would affect patient access to care in PBDs or the differences between the patients treated at PBDs and physician-owned offices. Reduced payments to off-campus PBDs have been impeding the ability of essential hospitals to provide care to vulnerable patients in these facilities.

By paying non-excepted PBDs at 40 percent of the OPSS rate, CMS grossly undercompensates essential hospitals for services they provide to complex patients. **We urge CMS to increase the payment rate for non-excepted PBDs of essential hospitals to adequately account for the higher acuity of patients they treat compared with physician offices and promote access to care in the nation’s most marginalized communities.** Payment rates also should reflect the requisite resources, staff, and capabilities necessary for PBDs to both comply with other CMS regulations and provide high-quality care to all patients. Essential hospital PBDs offer culturally and linguistically competent care tailored to the disadvantaged patients in their communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wraparound services, essential hospitals incur higher costs than other facilities. By considering the recommendations above, CMS can lessen the negative effect of Section 603 on disadvantaged patients’ access to care.

- b. CMS should exempt essential hospitals’ excepted PBDs from its clinic visit policy.

Separately, CMS can ensure access for patients that rely on off-campus, excepted PBDs by excluding essential hospital PBDs from its discretionary clinic visit

policy. Since 2019, CMS has reduced payment rates for excepted PBDs under what it has called its method to control unnecessary increases in the volume of clinic visit services furnished at these off-campus, excepted PBDs. The stated rationale behind this policy has been that hospitals' utilization related to the clinic visit service has increased rapidly compared to other services and resulted in shifts in sites of service from other lower-cost settings. As explained previously in this section, PBDs serve a unique role in their communities, incurring costs and providing services freestanding physician offices do not provide. In essential hospitals' communities in particular, their diverse patients turn to these PBDs as a source of primary and specialty care to which they would otherwise not have access. As described in section 1, essential hospitals are anchor institutions for their marginalized patients, providing a range of services and serving low-income patients. Their payer mix results in narrow financial margins relative to other hospitals—this tenuous financial predicament is only worsening due to the new pressures imposed by COVID-19 and unprecedented workforce and supply challenges.

Once CMS has defined the group of essential hospitals that serve a safety net role, it can use this definition to exempt associated PBDs from the clinic visit policy. Because the clinic visit policy is a discretionary policy CMS has implemented since 2019—not one mandated by statute—CMS can use its regulatory authority to reverse the cuts for essential hospitals' PBDs. In fact, in this very rule, CMS proposes to exempt PBDs of rural sole community hospitals (SCHs), highlighting their financial troubles, as well as unique access challenges their patients face, noting they “are often the only source of care in their communities.” These challenges are not dissimilar to the struggles essential hospitals face across the country. The difference is that SCHs are easily identified because there is an existing definition to capture the hospitals that fall into this group. Essential hospitals face equally dire financial challenges and have patients who similarly rely on their PBDs as their usual source of care. **Therefore, CMS should define a group of essential hospitals and exclude those essential hospitals' excepted PBDs from its clinic visit policy to ensure continued access for marginalized communities without other reliable sources of care.**

5. CMS should implement Section 603 of the BBA consistent with the legislative text to minimize the adverse effect on patient access.

In drafting the BBA, Congress left some specifics of Section 603 implementation for CMS to clarify through the rulemaking process. However, in its interpretation, the agency unnecessarily expanded the law's scope beyond Congress' legislative text and original intent; this will further harm essential hospitals and the marginalized patients they serve. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation and change of ownership.**

- a. CMS should allow PBDs to retain their excepted status notwithstanding relocation.

CMS should allow PBDs to retain their excepted status, even if they relocate, if they continue to meet the provider-based requirements. In the CY 2017 OPPI final rule, CMS created a limited extraordinary circumstances exception that allows a PBD to temporarily or permanently relocate without forfeiting excepted status. However, the exceptions process only covers a few scenarios and does not envision the many reasons for which a PBD might need to relocate. The BBA neither contemplated nor required that PBDs would lose their excepted status if they relocated.

There are many external forces that could compel a hospital to relocate a clinic. One of the most glaring examples has been the need for hospitals to relocate PBDs during the COVID-19

pandemic to increase access for patients and to triage care. In recognition of the need for hospitals to relocate PBDs during the pandemic, CMS allowed on-campus PBDs and excepted off-campus PBDs to relocate while maintaining their excepted status during the COVID-19 PHE. However, this relocation exception is temporary, and CMS will require hospitals to move the PBD back to its original location once the COVID-19 PHE expires. To allow hospitals to meet the needs of their communities and to respond to new outbreaks of COVID-19 or other future public health crises, CMS should allow hospitals to permanently relocate their PBDs once the COVID-19 PHE expires if it is in the best interests of their patients and communities.

There are other reasons a hospital might need to relocate its PBDs. For example, when a provider's lease for a PBD expires, it might find the renewal terms unsustainable. As landlords realize that CMS policy effectively makes a PBD a captive audience, they are likely to raise the rent. While any reasonable business facing such unfavorable economic conditions would consider relocation as a response, a PBD might simply close, given the lack of a financially viable alternative under the proposed relocation policy. Other reasons for relocation beyond a provider's control could include a building being closed for reconstruction or demolition, local zoning changes or ordinances, or other state and local laws. CMS' limitation on relocation is guided by the agency's belief that hospitals are motivated only by financial considerations. As these examples show, there are many reasons a provider might have to relocate that fall outside the agency's narrow exception.

For these reasons, CMS should lift the burdensome limitation on relocation and clarify that a hospital can relocate an excepted PBD if it continues to meet the provider-based requirements.

- b. CMS should permit excepted PBDs to retain their excepted status if they change ownership.

In the CY 2017 OPPS final rule, CMS finalized a policy that allows a PBD to maintain excepted status only if the main provider that owns the PBD changes ownership and the new main provider accepts the existing Medicare provider agreement. In scenarios in which the main provider does not change ownership but an individual PBD does, CMS states the PBD would lose its excepted status. **We recommend that CMS extend the policy on changes of ownership to circumstances in which an individual PBD changes ownership.** It is not uncommon for provider-based facilities to change hands over time for various reasons. For example, a hospital that finds operating an off-campus PBD unsustainable for financial or other reasons might decide to sell that particular PBD. But if the loss of excepted status makes the PBD unattractive to potential buyers, the hospital might close it. In such a case, patients in the community would lose access to vital outpatient services. Because excepted PBDs that change ownership operated before the date of enactment and are not newly created, they should remain excepted.

6. CMS should finalize permanent OPPS payment for remote mental health services, work to expand the list of reimbursable services, and provide additional flexibility that would encourage the provision of mental health services.

CMS proposes three payment codes for the diagnosis, evaluation, or treatment of mental health disorders performed remotely by clinical staff of a hospital using communications technology when the beneficiary is home. **We urge the agency to finalize payment for these codes**

and provide additional flexibility to allow hospitals to leverage their clinical staff to provide these services.

Medicare typically pays for remote services provided by eligible practitioners using interactive telecommunications technology as telehealth services under the PFS. During the COVID-19 PHE, CMS has used its blanket waiver authority to allow hospital outpatient departments to bill under the OPSS for remote mental health services that are not reimbursable under the PFS as telehealth services because, for example, the practitioner providing the service is not an eligible practitioner under telehealth reimbursement rules. CMS proposes to continue this flexibility once the COVID-19 PHE expires by permanently reimbursing for certain services provided remotely by clinical staff of a hospital. To qualify for reimbursement, CMS proposes that there would have to be no reimbursement through the PFS, the beneficiary must be in their home at the time of the service, the practitioner must be licensed to perform the services under relevant state laws, and the hospital clinical staff would have to be physically located in the hospital while providing the service using communications technology.

America's Essential Hospitals supports CMS' proposal to extend payment for remote mental health services to the OPSS. This would provide coverage for critical services provided by practitioners such as licensed professional counselors and marriage and family therapists. Providing payment for these services when not reimbursed through the PFS also will be critical to the continuity of care for patients who relied on these services during the COVID-19 PHE, particularly those with limited access to transportation and other social risk factors impeding their ability to travel to a hospital outpatient department.

CMS seeks comment on the requirement that the clinical staff be in the hospital while providing the remote service. **We urge CMS to remove this requirement, because hospital clinical staff providing mental health services have been able to leverage technology to provide services remotely while they are located in other settings, including their home.** This has been an indispensable part of essential hospitals' care delivery model for mental health services during the COVID-19 PHE, and requiring hospitals to revert to having their staff in the hospital for these services would be disruptive. For example, amid severe workforce shortages, one essential hospital has been able to expand its behavioral health workforce by allowing some mental health providers to work from home, which creates space in their outpatient departments for other vital staff who need to be physically onsite. CMS can allow hospital clinical staff to provide these services while in locations other than the hospital, as these staff fall under general supervision requirements, meaning the physical presence of a physician in the same location is not necessary. Additionally, with the ability of staff to securely access communications technology from home, including being able to access the hospital's electronic health record, clinical staff's presence in the hospital during the provision of a mental health service is not always necessary.

Therefore, we welcome CMS' addition of new reimbursement codes for the provision of remote mental health services, with the suggested revision of the requirement that the clinical staff be present in the hospital. We also encourage CMS to continue to identify additional services that are not reimbursed as telehealth services through the PFS that can be provided as remote services through the OPSS. Doing so will help expand access for marginalized communities that have benefited from accessing these services from their home.

7. CMS should withdraw its policy of requiring prior authorization for Medicare services for which, it states, there are unnecessary increases in utilization.

CMS proposes to require prior authorization for an additional category of services—facet joint interventions—beginning March 1, 2023. In the CY 2020 final rule, CMS for the first time required prior authorization for OPPS services. CMS cited section 1833(t)(2)(F) of the SSA as its authority for implementing prior authorization, which is the same authority the agency cited for implementing its payment cut for clinic visits at excepted off-campus PBDs. The addition of the facet joint intervention category is in addition to the seven categories of services for which CMS previously finalized a final authorization requirement. **We urge the agency not to finalize this proposal and to withdraw its entire prior authorization policy for OPPS services because the agency does not have the statutory authority to implement the policy, it hinders patient access to timely care, and it imposes excessive administrative burden on the agency and hospitals.**

- a. CMS' prior authorization policy is a violation of its statutory authority to control for increases in the volume of outpatient services.

Since CMS first finalized the OPPS prior authorization process, it has cited as its authority the provision of the SSA that allows it to “develop a method for controlling unnecessary increases in the volume” of OPPS services. This is the same provision CMS cited in making payment cuts to excepted off-campus PBDs. As we have established in previous years’ comments on that policy, the volume control methodology CMS invokes does not give the agency unlimited authority to target specific services for payment cuts or utilization control methods.⁴¹ Instead, it requires CMS to set target utilization rates, and only once those target rates are exceeded can CMS then apply a volume control method through a conversion factor adjustment.

CMS must first demonstrate that certain services have experienced unnecessary increases in volume before it can use this authority. In this instance, CMS has not shown unnecessary increases in facet joint interventions. CMS looks at data from 2012 to 2021 and points to increases in volume relative to overall OPPS services. However, there are many reasons for increase in utilization of outpatient services. For example, CMS failed to consider developments in clinical research that demonstrate the benefits of such services and drive utilization. CMS also did not consult with clinical experts who could explain the necessity of these services and the evolution in their use over the past decade. The facet joint intervention category contains a total of 10 services that are types of facet joint injection, medial branch block, and facet nerve destruction procedures. These are critical pain management procedures performed by providers to diagnose and mitigate sources of pain and are used independently or in conjunction with other pain management techniques.

Prior to CY 2020, CMS only required prior authorization for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) but not for OPPS services. However, it is granted explicit statutory authority for prior authorization under the DMEPOS fee schedule, which it does not have under the OPPS statute. Section 1834(a)(15) of the SSA clearly gives CMS the ability to require authorization for certain DMEPOS items by developing and updating a list of services to be subject to prior authorization. The volume control methodology CMS cites under the OPPS does not confer the same authority to the agency to use prior authorization. Even if it were to use prior authorization, CMS would have to demonstrate that

⁴¹ America’s Essential Hospitals Comment Letter on CY 2021 OPPS Proposed Rule. October 5, 2020. <https://essentialhospitals.org/wp-content/uploads/2020/10/AEH-CY2021-OPPS-Comment-Letter-10-5-20-unsigned.pdf>.

the increase in utilization was unnecessary, which it has not done in the rule. **Therefore, CMS should not finalize its proposal to add facet joint interventions to the list of services requiring prior authorization.**

b. Prior authorization requirements impede patient access to medically necessary care.

CMS' prior authorization process results in delays in patients accessing timely care, including in cases of genuine medical necessity. For a hospital to receive Medicare reimbursement for one of the services on CMS' list, it first must submit a prior authorization request to CMS or its contractors, which will have 10 business days to review the request before responding with a decision. If the service is approved, the provider will receive a provisional affirmation. However, payment for the service may still be denied once the hospital submits a claim for the service. In cases for which a hospital requests an expedited review due to risks to the beneficiary's life, health, or ability to regain maximum function, CMS or the contractor has two business days to respond with a decision. This timeline can seriously jeopardize beneficiary access to care, even in cases of expedited review. For example, in a case where a beneficiary presents to a hospital outpatient department with a condition that requires immediate treatment on a Friday afternoon, CMS would have until Tuesday—four calendar days later—to respond with a decision. This scenario does not account for additional time the provider will need to gather the necessary documentation and submit the required prior authorization paperwork. Additionally, there is no appeals process through which a provider could contest an adverse decision from CMS once a denial is issued. **CMS should withdraw the broader prior authorization policy because it creates unnecessary obstacles to Medicare beneficiaries receiving timely care deemed necessary by experienced clinicians.**

c. CMS' prior authorization policy is administratively burdensome for hospitals, their staff, and the agency.

CMS' proposal is administratively burdensome for providers and for the agency. It is operationally complex, is bound to increase regulatory burden, and will strain hospital systems and staff resources. Before a service is provided to a beneficiary, the provider must submit a detailed prior authorization request with documentation demonstrating the service meets Medicare coverage, coding, and payment rules. Hospital staff will require extensive training on the list of services subject to prior authorization, as well as the procedures for submitting these requests. Providers also will need to spend time explaining to patients the need for prior authorization and will need to develop educational materials for patients on these new requirements. The proposal also will strain CMS and its contractors' resources at a time when they already face a backlog of case reviews. **For these reasons, CMS should not finalize its prior authorization proposals in the rule and should withdraw its unlawful and burdensome prior authorization policy.**

8. CMS should withdraw its proposal to change the calculation of reimbursable organ acquisition costs at transplant centers.

In the rule, CMS proposes new policies on the inclusion of administrative and general (A&G) costs related to organ acquisition and seeks comments through a request for information (RFI) on a new methodology for calculating the Medicare share of organ acquisition costs. **We urge CMS to withdraw the policies we describe in additional detail below, because they would threaten the stability of these transplant hospitals and impose substantial additional burden on them.**

CMS should withdraw its proposal to require transplant hospitals to exclude the costs associated with receiving organs from an organ procurement organization (OPO) or other transplant hospital from organ acquisition costs. Under CMS' policy for calculating organ acquisition costs, transplant hospitals report on their Medicare cost report the A&G costs for overhead related to procuring an organ. Reporting these costs allows these costs to be included in Medicare's cost-based reimbursement for organ acquisition costs. When transplant hospitals receive an organ from an OPO or other transplant hospital, they incur A&G costs related to procuring the organ, but CMS proposes that these costs be excluded from the receiving transplant hospital's A&G costs on the cost report, which would preclude transplant hospitals from receiving reimbursement for the overhead costs related to receiving these organs. **We urge CMS to withdraw this policy, which would exclude significant costs associated with organ transplantation and is contrary to longstanding transplant hospital practices.**

Transplant hospitals that receive an organ from another transplant hospital or an OPO incur costs related to preparing an organ for transplantation, even if the organ is purchased from an OPO or another transplant hospital and not excised at the receiving transplant hospital. CMS proposes its policy under the assumption that the costs of procuring the organ are already accounted for in the procuring OPO or transplant hospital's A&G costs. However, independent OPOs and transplant hospitals have completely separate A&G infrastructures with distinct costs. The receiving transplant hospital incurs administrative expenses related to processing complex invoices from the OPO, the procuring surgeon, the transportation company, and other stakeholders involved in the transplant purposes. The costs of the OPO and the receiving hospital are accounted for separately, with the OPO reporting its own costs and the transplant hospital reporting its own associated costs. By excluding the transplant hospital's A&G costs, CMS would omit significant expenses that transplant hospitals incur in receiving and preparing organs for transplantation. **To ensure transplant hospitals are adequately reimbursed for all the costs they incur in preparing an organ for transplantation, CMS must include these A&G expenses in the organ acquisition calculation.**

In a request for information on a separate policy related to organ acquisition costs, CMS seeks comment on changing its decades-old policy on how transplant centers are reimbursed for the cost of organ acquisition. Medicare's long-standing policy is to reimburse transplant centers and organ procurement organizations (OPOs) for the cost of excising donor organs under the assumption that most excised organs will eventually be transplanted into a Medicare beneficiary. CMS seeks comments on changing the calculation of the Medicare share of excised organs to permit transplant centers only to claim the costs of organs that are excised and that are transplanted into a Medicare beneficiary at the same transplant hospital. Under such a policy, organs eventually transplanted into beneficiaries at other transplant hospitals would not be included. By limiting transplant centers' Medicare share of allowable organ acquisition costs to only those organs that end up being transplanted into a Medicare beneficiary at the same hospital, CMS would reverse longstanding policy and undermine the organ donation program and viability of transplant centers.

Transplant centers would be responsible for tracking an organ from its donor to its recipient to determine which organs are eventually transplanted into a Medicare beneficiary at the hospital, which is not administratively feasible. When many transplant centers excise an organ, they send the organ to an OPO, which identifies a recipient transplant center and sends the organ to that center, even if the organ ends up being transplanted into a recipient at the same transplant center. The OPO, not the hospital, is responsible for identifying a recipient. Transplant centers would have to work with OPOs to determine the ultimate destination of each organ that was

excised at the transplant center. This would be an extremely cumbersome process that also raises patient privacy implications. Medicare is seeking comment on reducing reimbursement for these organs under the assumption that other payers, including Medicaid, will assume the costs of organ acquisition. This is a bold assumption that is unlikely to materialize. Transplant centers would need to negotiate contracts with other payers and determine a reimbursement model for the acquisition of these organs—a process that will require substantial time.

The reduced reimbursement and added burden associated with this policy would cause many transplant centers to cease or limit operations and would decrease the number of organs excised for donation, thus undermining the organ donation program and health of potential organ recipients. Moreover, the reduction in available organs would result in higher costs to Medicare in the form of more costly treatment—for example, fewer available kidneys might result in more treatment and dialysis for patients with end stage renal disease. Given the potential adverse consequences, CMS should not propose such a policy, which will undermine the goals of the organ acquisition and transplant system.

9. CMS should continue to refine the Outpatient Quality Reporting (OQR) Program to include measures that provide valid, accurate, and meaningful information to consumers about care quality and ensure essential hospitals are provided flexibility as they recover from the COVID-19 PHE.

CMS should continue to tailor the Hospital OQR Program measure set to include measures that are useful to hospitals as they work to improve the quality of their care and beneficial to the public as an accurate reflection of the care hospitals provide. America's Essential Hospitals supports the creation and use of measures that lead to quality improvement. We encourage CMS to verify measures would not lead to unintended consequences before including them in the OQR Program and to consider the ongoing impact of COVID-19 and its impact on hospital operations, including quality improvement.

CMS is not proposing additions to the CY 2023 OQR Program measure set. The agency does propose to change one cataract measure from mandatory to voluntary reporting and seeks comment on the future inclusion of a volume indicator measure. We ask CMS to consider the following comments as it continues to refine the OQR Program to ensure measures are reliable, valid, and useful in improving the quality of hospital care and the transparency of public reporting.

a. CMS should change the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (OP-31) measure from mandatory to voluntary.

The OP-31 measure was originally adopted in the CY 2014 OPSS final rule. The measure evaluates the percentage of patients who had improvement in visual function achieved within 90 days following cataract surgery, based on completing both a pre- and post-operative survey. The measure has been voluntarily reported for several years. In last year's OPSS proposed rule, CMS stated it would be appropriate to require hospitals to report on OP-31 for the CY 2023 reporting period. However, after receiving comments expressing concern about making this measure mandatory, given the additional burden reporting the measure would create during the COVID-19 pandemic, CMS finalized a two-year delay in implementing this measure, with mandatory reporting set to begin in CY 2025.

Hospitals nationwide continue to respond to COVID-19 cases while also trying to recover from the impacts of the pandemic. Given the continued strain on hospitals, including staffing

shortages, CMS believes it is appropriate to change OP-31 from mandatory to voluntary reporting with the CY 2025 reporting period. No changes would be made to reporting for CY 2023 and 2024—i.e., the measure would remain voluntary during these years, as well.

Essential hospitals are facing dire workforce challenges as COVID-19 continues to shrink the workforce and heighten concerns about looming provider shortages in coming years. The pandemic has led to burnout on an unprecedented scale, and ongoing capacity challenges and the consequential emotional toll on staff remain evident. Measures that require cross-setting coordination among clinicians of different specialties (i.e., surgeons and ophthalmologists), such as OP-31, add complexity and burden to essential hospitals already under tremendous strain. **We support CMS’ proposal to change the OP-31 measure from mandatory to voluntary beginning with the CY 2025 reporting period.** Further, we encourage CMS to consider withdrawing or permanently suspending the measure because compliance will place unnecessary and administratively burdensome responsibilities on essential hospitals without associated improvements in patient care.

- b. CMS should refrain from reimplementing the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) and not to include a volume indicator measure in the Hospital OQR Program unless there is evidence linking the measure to improved clinical quality and after obtaining NQF endorsement.

The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume. However, it previously did. In the CY 2012 OPSS final rule, CMS adopted OP-26, a structural measure that collected surgical procedure volume data on eight categories of procedures frequently performed in the hospital outpatient setting. Then, in the CY 2018 OPSS final rule, CMS removed OP-26, stating, “there is a lack of evidence to support this measure’s link to improved clinical quality.”⁴²—specifically, that the number of surgical procedures does not offer insight into a facility’s overall performance or quality improvement. Further, CMS reasoned that the burden of reporting this measure outweighs any potential value. In the proposed rule, CMS does not offer any new evidence to support a link between OP-26 and improved clinical quality. As such, **we urge CMS to refrain from reimplementing OP-26 in the Hospital OQR Program.**

Volume should not be substituted for properly risk-adjusted clinical outcomes as a measure of care quality. Volume often is used as a proxy measure for other factors that affect care. But those other factors (e.g., use of appropriate processes of care) might explain the underlying reasons for the volume-outcomes relationship and would not be captured by a volume indicator measure. CMS also notes that the ability for patients to track volume changes by facility and procedure could indicate to a patient which facilities are experienced with certain outpatient procedures. However, given the complex relationship between volume and quality, and the lack of evidence linking volume to improved clinical outcomes, the public reporting of volume as an indicator of where to seek care is misguided. **We caution CMS against reintroducing a volume indicator as a measure of care quality.**

Additionally, the National Quality Forum (NQF) Measure Applications Partnership (MAP) did not review or endorse OP-26. It is critical NQF review and endorse measures in the Hospital OQR Program. NQF endorsement and MAP approval are imperative to ensure measure validity

⁴² CY 2018 OPSS/ASC final rule. <https://www.govinfo.gov/content/pkg/FR-2017-11-13/pdf/2017-23932.pdf>. Accessed August 8, 2022.

and reliability. Through these processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders.

- 10. CMS should fully examine the impact of COVID-19 on underlying measure data and, if needed, suppress the Overall Hospital Quality Star Ratings to ensure consumers receive fair, accurate, and meaningful information.**

The COVID-19 PHE has had, and continues to have, significant and ongoing effects on care delivery nationwide. Challenges over the course of the COVID-19 PHE have included: shortages of personal protective equipment; issues related to hospitalizations and transfers; staffing and supply shortages; and funding scarcity. Further, because COVID-19 prevalence remains inconsistent across the country, hospitals in different areas have been affected differently at various times throughout the pandemic.

Due to the likelihood significant distortions in quality measurement will continue, CMS proposed and finalized in the FY 2022 IPPS rule to continue to apply its cross-program suppression policy. This policy will be applied in the Hospital Value-Based Purchasing Program and the Hospital-Acquired Condition Reduction Program. We appreciate CMS' recognition that hospitals in these quality programs should not be negatively affected when their quality performance suffers due to external factors rather than actual care provided. Similarly, for the Overall Hospital Quality Star Ratings beginning with CY 2021 and for subsequent years, CMS adopted a policy that it would consider suppressing the rating if extenuating circumstances affected numerous hospitals. These extenuating circumstances include a calculation error by CMS, a systemic error at the CMS quality program level, and a PHE that substantially affects the underlying measure data.

Since the emergence of the COVID-19 PHE, CMS has refreshed the Overall Star Ratings twice. However, both times almost all measures included in the refreshes used pre-COVID data due to CMS' issuing of a nationwide Extraordinary Circumstances Exception that exempted reporting requirements for Q1 and Q2 2022 data. CMS intends to publish ratings in 2023, unless it exercises its authority described above to suppress the ratings due to the COVID-19 PHE substantially affecting the underlying measure data.

We continue to believe there are potential implications of exempting quarters of data from reporting, such as measure reliability and accuracy in future public reporting. Further, the full impact of the COVID-19 pandemic on outcomes and quality measures is still unknown. It is important to closely examine performance measures and policies in Medicare that are tied to payment and publicly reported ratings. CMS must ensure the accuracy and completeness of data submitted. It is misleading to consumers to publish ratings based on data that has been substantially affected by the COVID-19 pandemic. **We urge CMS to continue its measure reliability analyses, ensure it has sufficient data to calculate performance accurately, and suppress the ratings if analyses show an impact to the underlying measure data.**

- 11. CMS should remove services from the inpatient only (IPO) list based on established criteria for determining removal. The strategy for removal should ensure patient safety and account for impacts to patient mix in Medicare payment models.**

Procedures on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates—not paid for under the OPSS. Each year, CMS

reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting. In the CY 2022 OPSS final rule, CMS reversed its decision to eliminate the IPO list and finalized a proposal to codify five longstanding criteria for determining whether a service or procedure should be removed from the IPO list. We support the return to a more thoughtful, gradual approach, including systematic evaluation of each service before proposing to remove it. Along with physician judgment, the IPO list serves as a tool to indicate which services are appropriate to furnish in the outpatient setting. **We urge CMS to continue to study the differences in performing procedures in both settings to ensure patient safety for all Medicare beneficiaries.**

For CY 2023, CMS proposes to remove 10 services from the IPO list, including maxillofacial procedures and other services originally removed from the IPO list in CY 2021, but then returned to the list for CY 2022 when the elimination of the IPO list was halted. These services each have undergone in-depth clinical review and evaluation, using longstanding criteria for determining whether a procedure should be removed from the IPO list, including that the procedure can be appropriately and safely furnished in an outpatient setting. Further, several of the services proposed for removal are related to codes CMS already has removed from the IPO list. **America's Essential Hospitals supports the removal of these services with the goal of providing more choice to patients and providers regarding care setting.**

When services are removed from the IPO list, providers need time to prepare clear criteria for surgical site selection, develop criteria for patient selection, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the Inpatient Prospective Payment System (IPPS) or OPSS. **We encourage CMS to provide adequate time and guidance to providers before removing procedures from the IPO list.**

We also continue to have concerns about the effect of removing services in current Medicare payment models from the IPO list. As CMS contemplates future removal of procedures from the IPO list, we urge the agency to consider patients who previously would have received procedures included in Medicare models, such as the Bundled Payments for Care Improvement (BPCI) modes, in an inpatient setting that might receive those procedures on an outpatient basis if eliminated from the IPO list. This potential shift in care setting complicates the process for establishing an accurate target price based on historical data within CMS models. Further, the historical episode spending data might not accurately predict episode spending for beneficiaries receiving the procedure as an inpatient. **Removing procedures from the IPO list will require modifications to the current Medicare payment models**, leading to potential confusion among hospitals and CMS, as well as issues of accuracy and fairness in setting target prices. **We urge CMS to further examine the impact on Medicare models to ensure hospitals are not negatively impacted** by removal of services from the IPO list.

In many cases, there also are differences in patient population for procedures performed on an outpatient basis—i.e., younger, active, fewer complications, and having more support at home than most Medicare beneficiaries. Further, many Medicare patients have comorbidities and require intensive rehabilitation after certain procedures (e.g., TKA/THA) best performed in an inpatient setting. As such, certain procedures performed on an outpatient basis might only be appropriate for a small number of Medicare beneficiaries. We encourage CMS to work with stakeholders to identify a methodology for payment model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting. **We urge CMS to study the differences in performing procedures in both settings to ensure patient safety and fairness among**

participants in episode-based payment models, before removing services from the IPO list.

12. CMS should further examine ways to address health equity in the Hospital OQR Program, including stratifying measure performance by social risk factors beyond dual eligibility, refraining from the public reporting of disparities results, and considering additional hospital characteristics in the reporting of disparities.

As providers of care for marginalized and underrepresented communities, essential hospitals deeply understand the need to identify existing gaps in care quality and eliminate disparities, as a matter of public health. It is critical health equity is integrated and aligned across CMS programs. We applaud the administration's continued emphasis on health equity, including the proposed rule's RFI about overarching principles for measuring health care quality disparities across CMS quality programs and how to apply these principles to the Hospital OQR Program.

Since 2018, CMS has provided hospital-level confidential results stratified by dual eligibility for the six condition-specific readmission measures currently in the HRRP. These CMS disparity method reports are intended to educate hospitals and other stakeholders about the two disparity methods—within-hospital and across-hospital—and allow hospitals to review their results and data. In the CY 2022 OPPS proposed rule, CMS identified six priority measures in the Hospital OQR Program as candidates for disparities reporting stratified by dual eligibility. **We encourage CMS to include in its disparity methods reports social risk factors, beyond dual eligibility and race and ethnicity, to capture the full array of variables that might impact the quality of care.**

Essential hospitals are committed to transparency and accuracy in quality measurement. Our members understand the importance of quality improvement reporting, especially with increasing demands for accountability, movement toward value-based purchasing, and growing consumer engagement. Our members also know the importance of sound data to reduce disparities in care, and they lead efforts to close gaps in quality for racial and ethnic minorities.

Hospitals should be armed with as much meaningful information as possible to inform their decision-making and quality improvement efforts. The CMS disparity methods reports enable hospitals to internally examine their efforts to address disparities in the context of other hospitals in their region. Essential hospital leaders deeply understand the characteristics of the populations their hospitals treat and the challenges they face and are the best audience to view and interpret these reports. **We urge CMS to continue to confidentially report results to hospitals and refrain from public reporting.**

Further, as CMS evaluates opportunities to expand its measure stratification reporting initiatives, such as the disparity methods reports, **we encourage the agency to consider adding hospital characteristics to the confidential reporting of across-hospital disparity method results. We also encourage CMS to deem essential hospitals as a unique class of facilities for purposes of across-hospital reporting.** As outlined in section 1, essential hospitals play a distinct role in their communities, share a set of distinctive characteristics, and serve the marginalized and most at-risk patients. By formally defining essential hospitals, CMS could add this characteristic to its disparity methods reports to provide comprehensive information on disparities and support collaboration among hospitals working to improve equity.

America's Essential Hospitals and its members are committed to tackling these important topics and look forward to additional opportunities for stakeholder engagement.

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO